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| 09/919,877      | 08/02/2001  | Jerry Y. Jonn        | 104226.01           | 4857             |

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EXAMINER

CHOI, FRANK I

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1616

DATE MAILED: 07/02/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/919,877

Applicant(s)

JONN ET AL.

Examiner

Frank I Choi

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-27 and 46-72 is/are pending in the application.
- 4a) Of the above claim(s) 18-27 and 46-58 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 and 59-72 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-72 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Election/Restrictions***

Applicant's election with traverse of Group I in Paper No. 9 is acknowledged. The traversal is on the ground(s) that prosecution of the method claims would not constitute an undue burden. This is not found persuasive because in the first instance the generic claim is very broad in that the generic claim only requires that there be a first monomer species and a second different monomer species with different absorption rates. In the second instance, the process claims will of course be rejoined with allowable composition claims provided that withdrawn process claims depend from or otherwise include all the limitations of the allowable composition, however, the composition claims as currently set forth do not appear to be allowable. In the third instance, since the method claims require search of tissue adhesives, contrary to Applicant's arguments, the search of the composition claims and method claims are different. Therefore, in light of the breadth of the claims as a whole, prosecution of Groups I and II would constitute an undue burden. The process claims will of course be rejoined with allowable composition claims provided that withdrawn process claims depend from or otherwise include all the limitations of the allowable composition.

The requirement is still deemed proper and is therefore made FINAL.

***Claim Rejections - 35 USC § 102/103***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless —

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 8-11, 14, 17, 68, 69-71 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Berger et al. (US Pat. 5,998,472).

Berger et al. expressly discloses adhesive mixtures of different alkyl cyanoacrylate monomers which fall within the scope of applicant's claims (Column 9, lines 32-68, Columns 10-12, Example 1, Claims 1-21).

Alternatively, at the very least the claimed invention is rendered obvious within the meaning of 35 USC 103, because the prior art discloses products that contain the same exact ingredients/components as that of the claimed invention. See *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980). See also *In re May*, 197 USPQ 601, 607 (CCPA 1978).

Claims 1, 5, 6, 8-11, 14, 17, 68, 69, 72 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Akimova et al. (US 4,981,483) or EP 0 374 252 for the reasons of record set forth in the prior Office Action and the further reasons below.

Akimova et al. and EP 0 374 252 where discussed in the prior Office Action and the same are incorporated herein.

Examiner has duly considered Applicant's argument but deems them unpersuasive.

As indicated in *In re Fitzgerald* and *In re May*, in an inherency-based rejection under 102, the fact that a prior art reference does not describe or disclose a property of a claimed composition, the prior art composition will meet the claim if the property is inherent. Herein, the composition contains the same compounds as the claimed invention, as such, the prior art composition will have adhesive properties. The burden is on Applicant to show that the prior art composition does not have adhesive properties. Arguments of counsel do not constitute evidence. See *In re Schulze*, 145 USPQ 716, 718 (CCPA 1965); *In re Geisler*, 43 USPQ2d 1362 (Fed. Cir. 1997).

Claims 1, 5-11, 14, 17, 68-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Hawkins et al.* (US Pat. 3,591,676) in view of *Clark et al.* (US Pat. 5,981,621).

*Hawkins et al.* disclose the combination of methyl 2-cyanoacrylate with a higher ester of 2-cyanoacrylate, such as ethyl, butyl, hexyl, octyl, methoxybutyl and ethoxyethyl and that the combination results in retention of the beneficial properties of the monomers while reducing the undesirable properties, i.e. the retention of the biodegradability of the methyl 2-cyanoacrylate with reduction of the local reactions and retention of less local reactions found in the other esters while reducing the lower biodegradability (Column 1, Column 2, lines 1-29).

*Clark et al.* teach a composition comprising at least one monomer, such as alkyl ester cyanoacrylates and alkyl alpha cyanoacrylates, at least one plasticizer and a mixture of anionic and radical stabilizers, such as sulfur dioxide, hydroquinone, p-methoxyphenol and butylated hydroxyanisole (Column 2, lines 63-68, Columns 3-6). It is taught that in applying composition

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a polymerization initiator, such as benzalkonium chloride, is used and may be readily selected by one of ordinary skill in the art without undue experimentation (Column 11, lines 18-68).

The difference between the prior art and the claimed invention is that the prior art does not expressly disclose the use of additives such as anionic stabilizing agents, free radical stabilizing agents and plasticizers. However, the prior art amply suggests the same as it is known to use the same in cyanoacrylate adhesive compositions. As such, it would have been well within the skill of and one ordinary skill in the art would have been motivated to modify the prior art as above with the expectation that addition of said additives would modify the stability and plasticity of the composition as desired.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Claims 1-4,8-17,59-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clark et al. (US Pat. 5,981,621) in view of Kronenthal et al. (US Pat. 3,995,641), Collins et al. (Abstract) and EP 0 965 623 for the reasons of record set forth in the prior Office Action in further view of Hammerslag (US Pat. 6,386,203) and the further reasons below.

Clark et al., Kronenthal et al. Collins et al., and EP 0 965 623 were discussed in the prior Office Action and the same are incorporated herein.

Hammerslag teaches that polymerizable cyanoacrylates can be co-polymerized with other compounds that alter elasticity, modify viscosity and aid in biodegradation (Column 5, lines 21-33). It is taught that suitable cyanoacrylates can be chosen from methyl , ethyl, butyl, methoxypropyl, alkoxyalkyl, and carbalkoxyalkyl depending on acceptable toxicity and other

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properties for a give application (Column 5, lines 54-67). It is taught that there is a wide variation in the rates of biodegradation of cyanocrylates but generally polymers of cyanoacrylates which have substituents that are small an/or contain one or more oxygen-containing functional groups appear to have increased biodegradability rates whereas cyanoacrylates having long chain alkyl groups lacking in oxygen-containing functional groups as substituents tend to form polymers which biodegrade more slowly (Column 6, lines 33-45). It is taught that one of ordinary skill in the art would be able to by routine experimentation choose a cyanoacrylate with suitable biodegradation characteristics (Column 6, lines 49-56).

The difference between the prior art and the claimed invention is that the prior art does not expressly disclose a composition or film having a first monomer and a different second monomer where the absorption rate of the first monomer species is different from the absorption rate of the second monomer species. However, the prior art amply suggests the same as it is known in the art to combine different monomers in forming medical adhesives. Further, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to combine an alkyl ester cyanoacrylate with an octyl 2-cyanoacrylate with the expectation that absorption of the composition could be adjusted readily by modifying the ratio of the two monomers and the composition would have low toxicity. Further, one of ordinary skill in the art would have been motivated to combine sulfur dioxide and sulfuric acid with radical stabilizers such as hydroquinone, p-methoxyphenol and butylated hydroxyanisole with the expectation that the composition would be more stable.

Examiner has duly considered Applicant's arguments but deems them unpersuasive.

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In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Further, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). In this case, it is known in the art that different types of cyanoacrylates have different biodegradation rates and that cyanoacrylates can be co-polymerized with other compounds to modify the biodegradation rate, as such, it would have been well within the skill of an one of ordinary skill in the art would have been motivated to modify the prior art as with the expectation that biodegradation rates could be modified by combining different monomers having different biodegradation rates. Also, disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. In *re Susi*, 69 USPQ 423 (CCPA 1971). "A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." In *re Gurley*, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994).

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.



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Claims 1,5-11,14,17,68-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clark et al. (US Pat. 5,981,621) in view of Banitt (US Pat. 3,559,652), Collins et al. (Abstract) and EP 0 965 623 for the reasons of record set forth in the prior Office Action in further view of Hammerslag (US Pat. 6,386,203) and the further reasons below.

Clark et al., Banitt, Collins et al. and EP 0 965 623 were discussed in the prior Office Action and the same are incorporated herein.

Hammerslag is cited for the same reasons as above and the same is incorporated herein to avoid repetition.

Examiner has duly considered Applicant's arguments but deems them unpersuasive for the same reasons as above.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

### ***Conclusion***

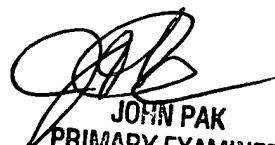
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (703) 308-0067. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. Thurman Page, can be reached on (703) 308-2927. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (703) 308-1235 and (703) 308-0198, respectively.

FIC

June 28, 2003



JOHN PAK  
PRIMARY EXAMINER  
GROUP 1600